

Wake Forest Institute for Regenerative Medicine



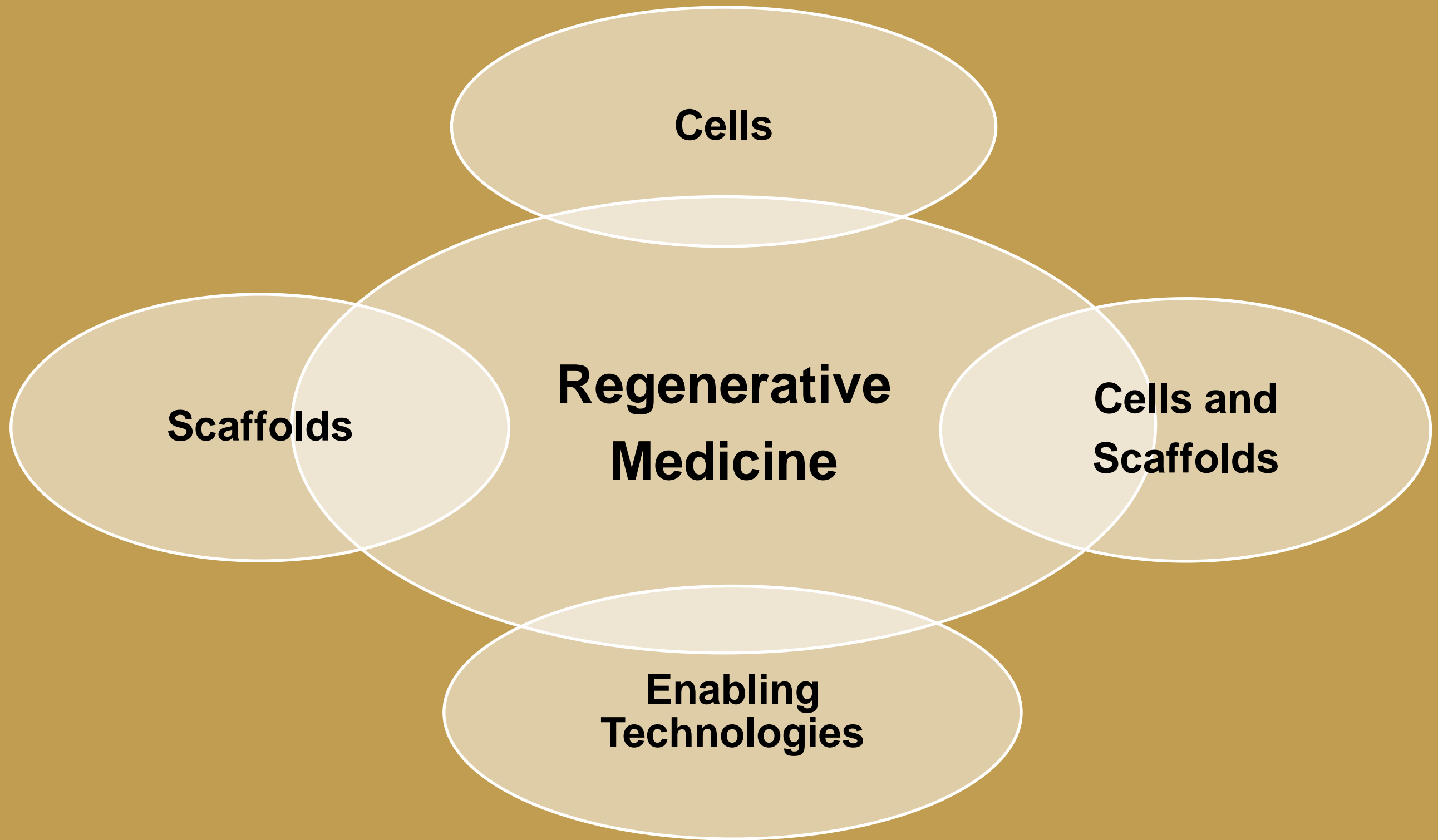
Our Mission

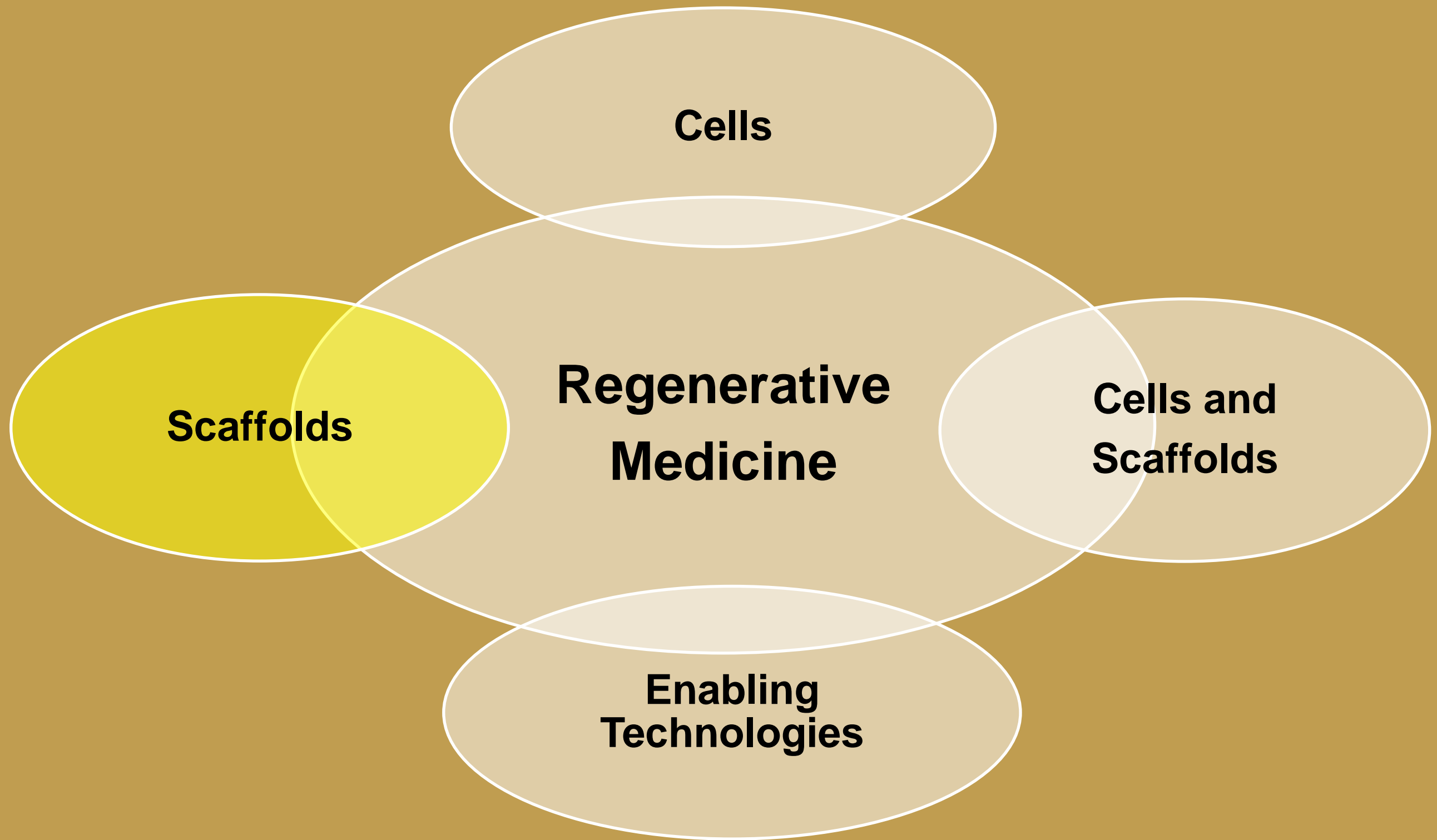
Improve patients' lives by developing regenerative medicine therapies and support technologies.

First Organ Transplant, Boston MA 1954



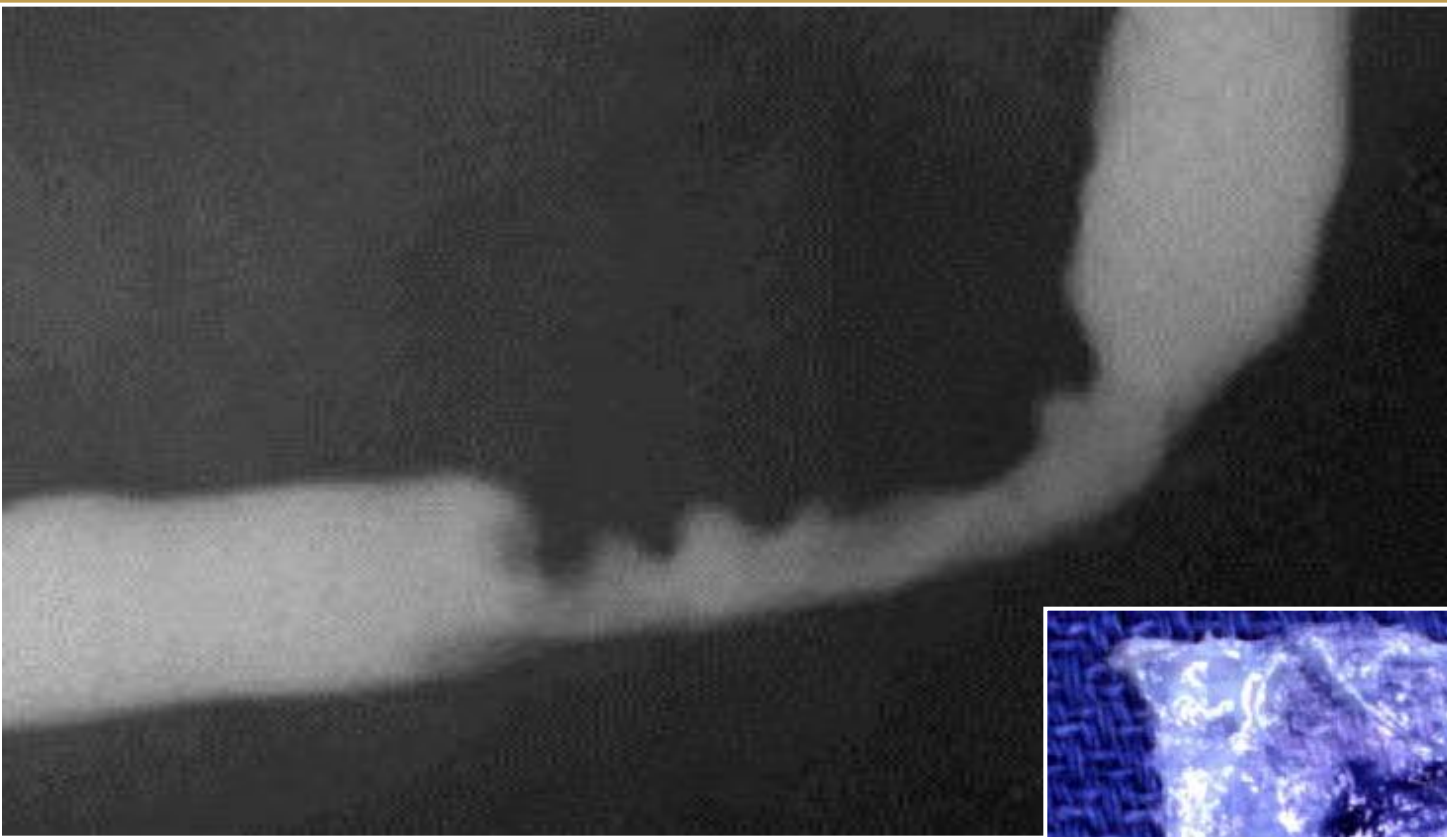
Every 30 seconds,
a patient dies from
diseases that could be treated
with tissue replacement



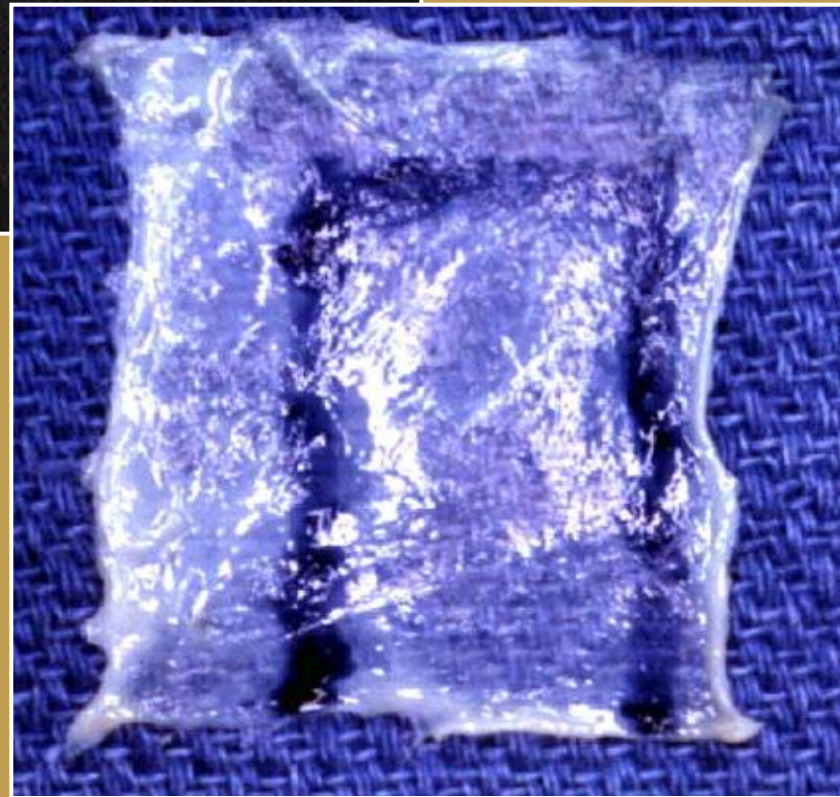


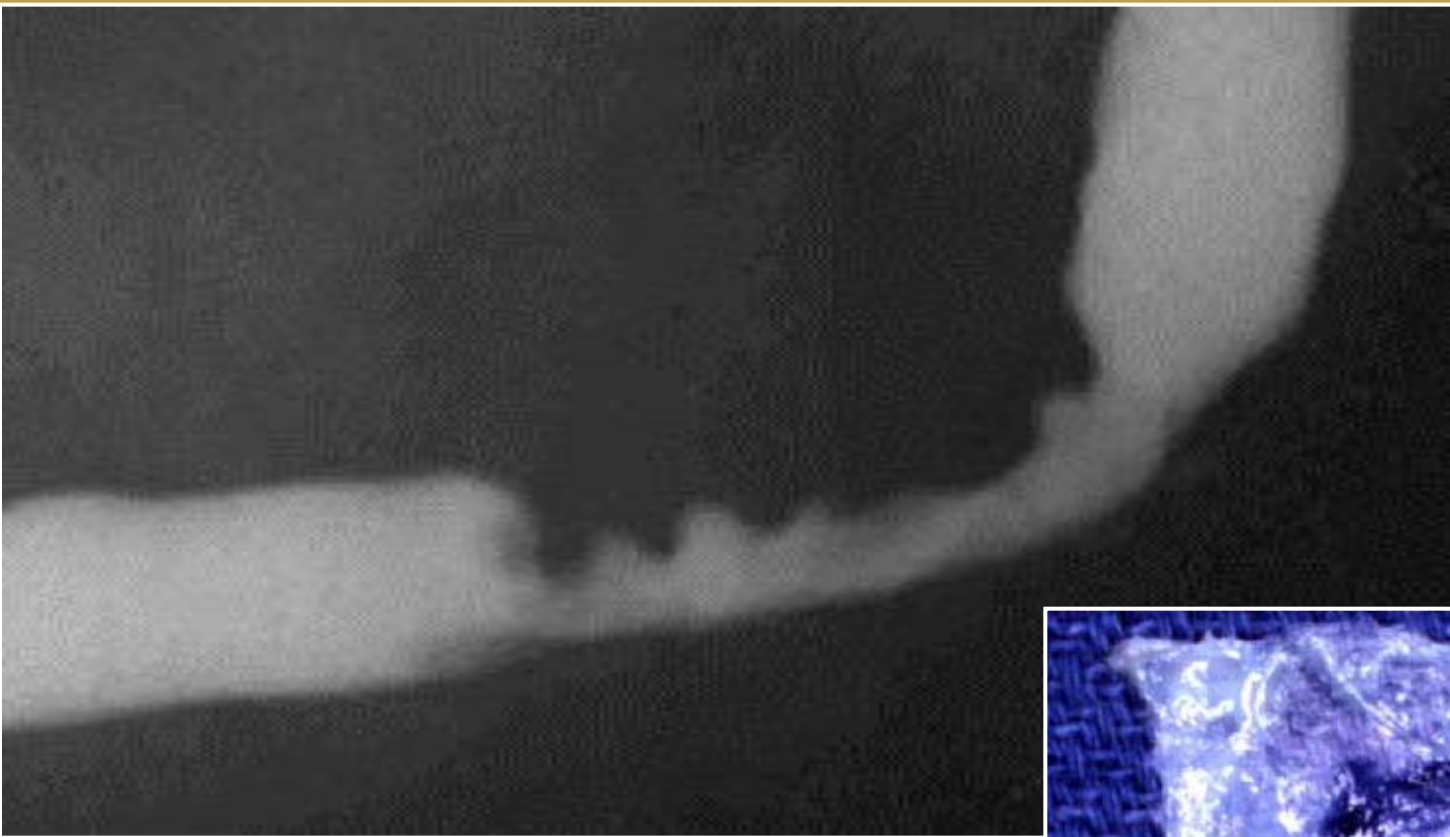


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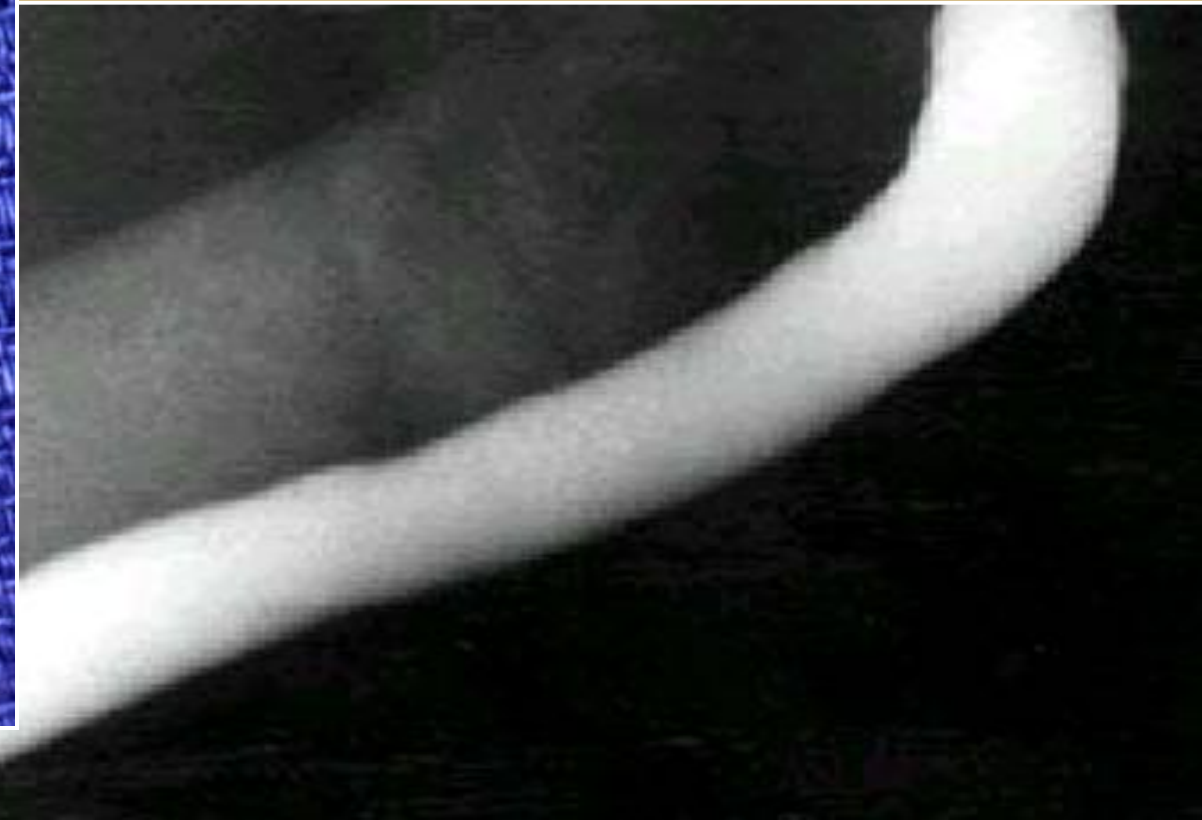
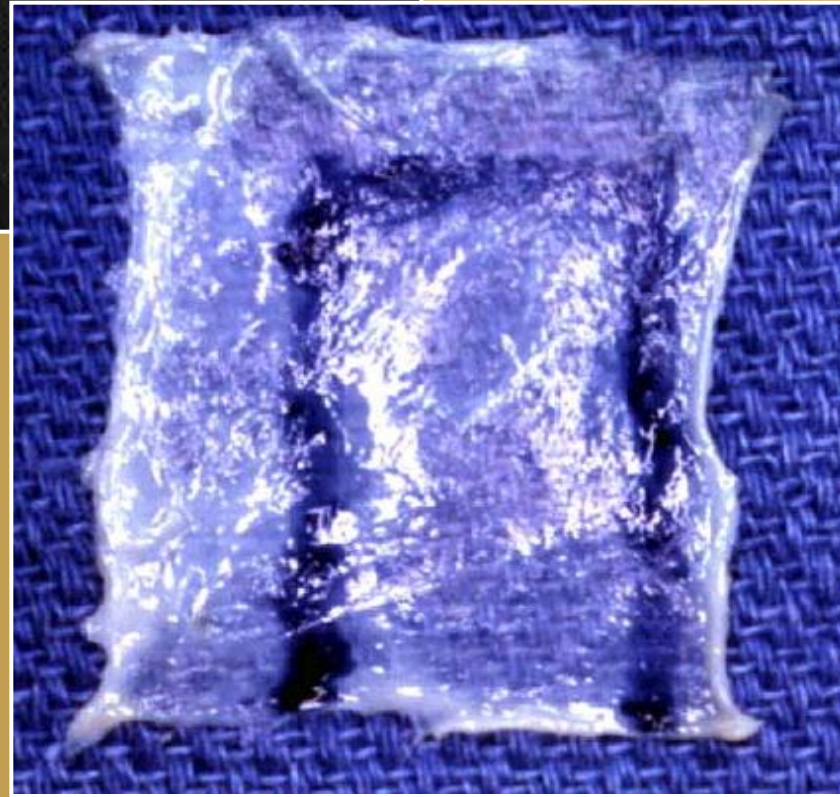


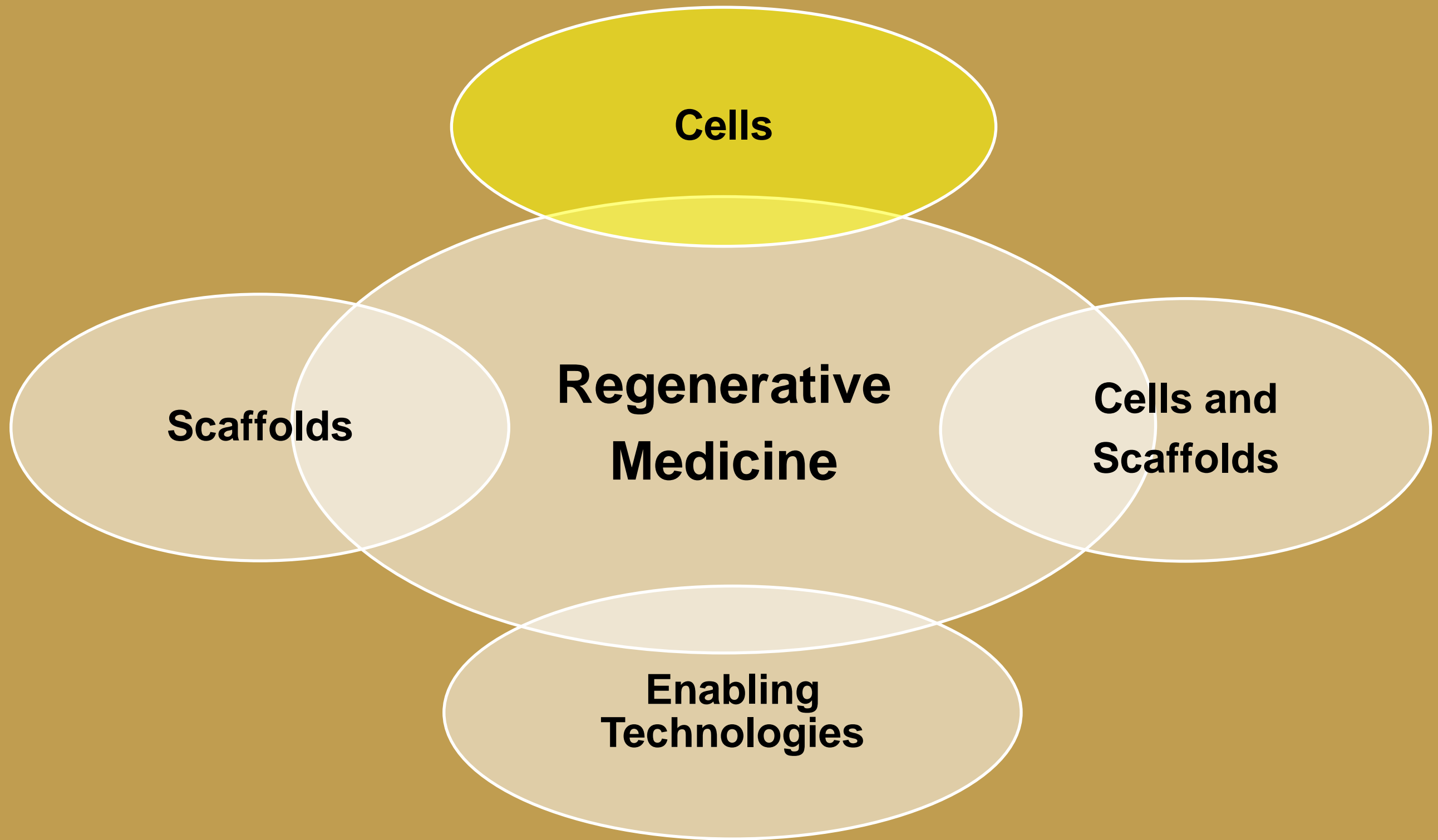
First use of a natural biomaterial
in humans for tissue
regeneration, 1996

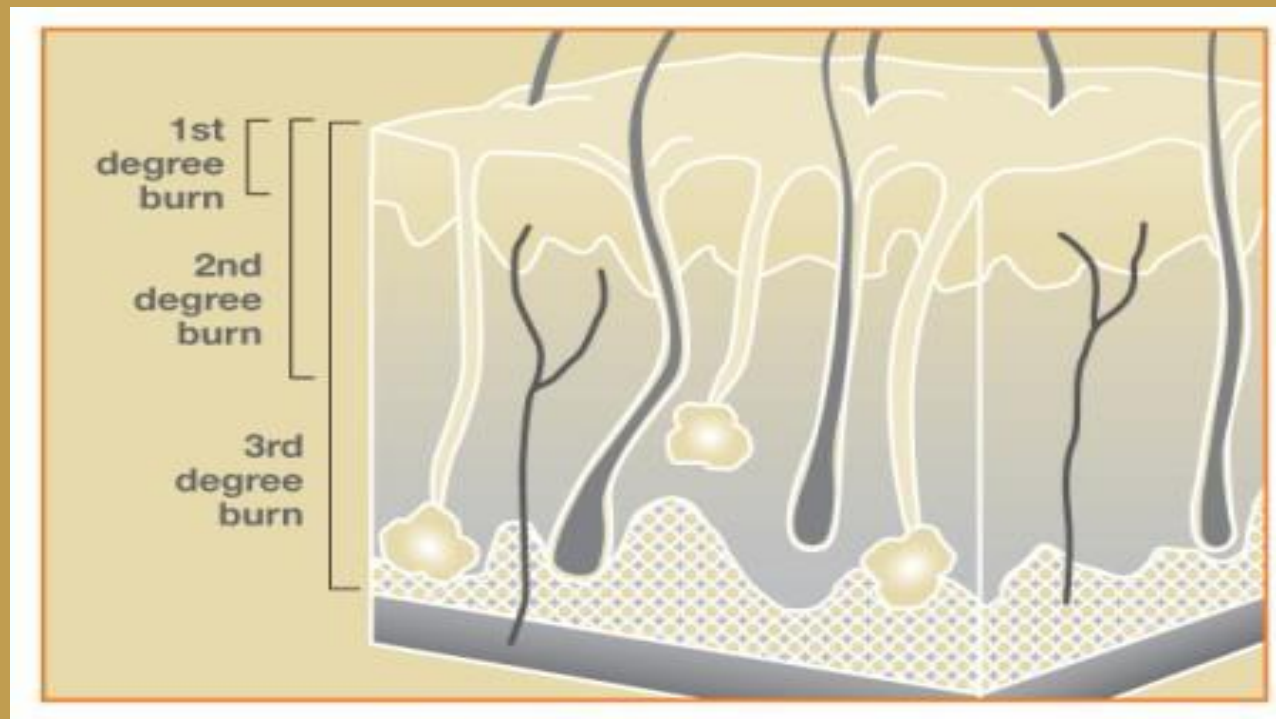




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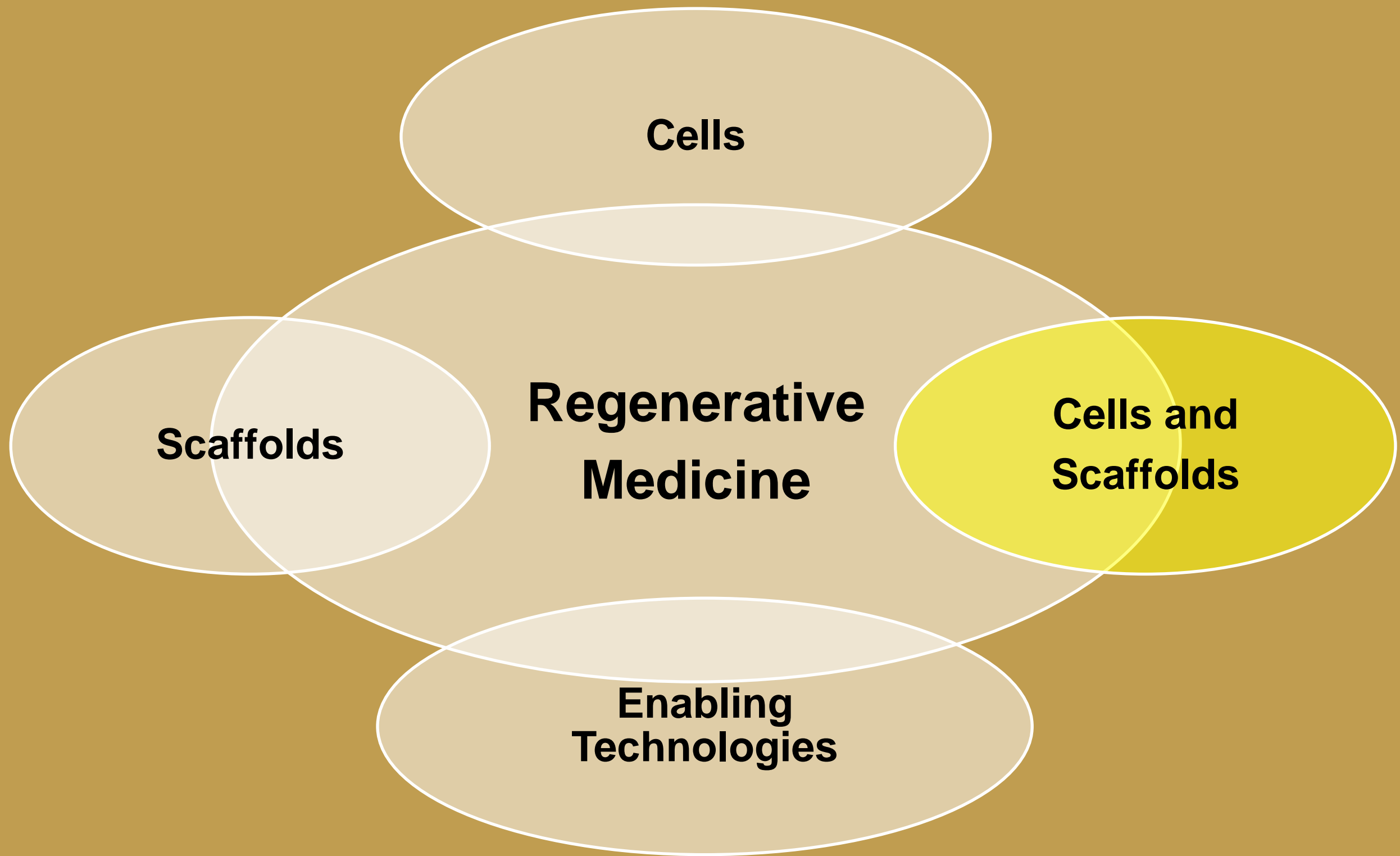


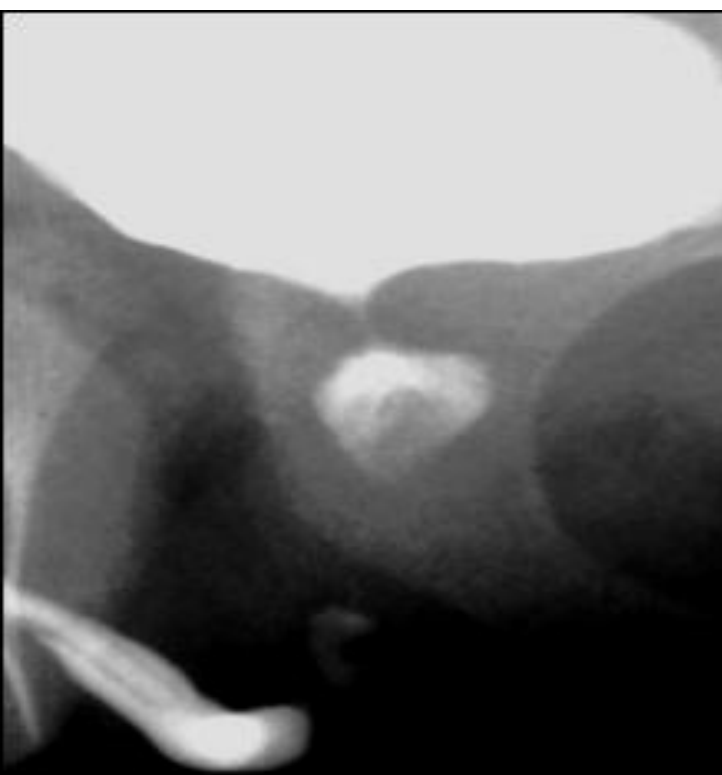


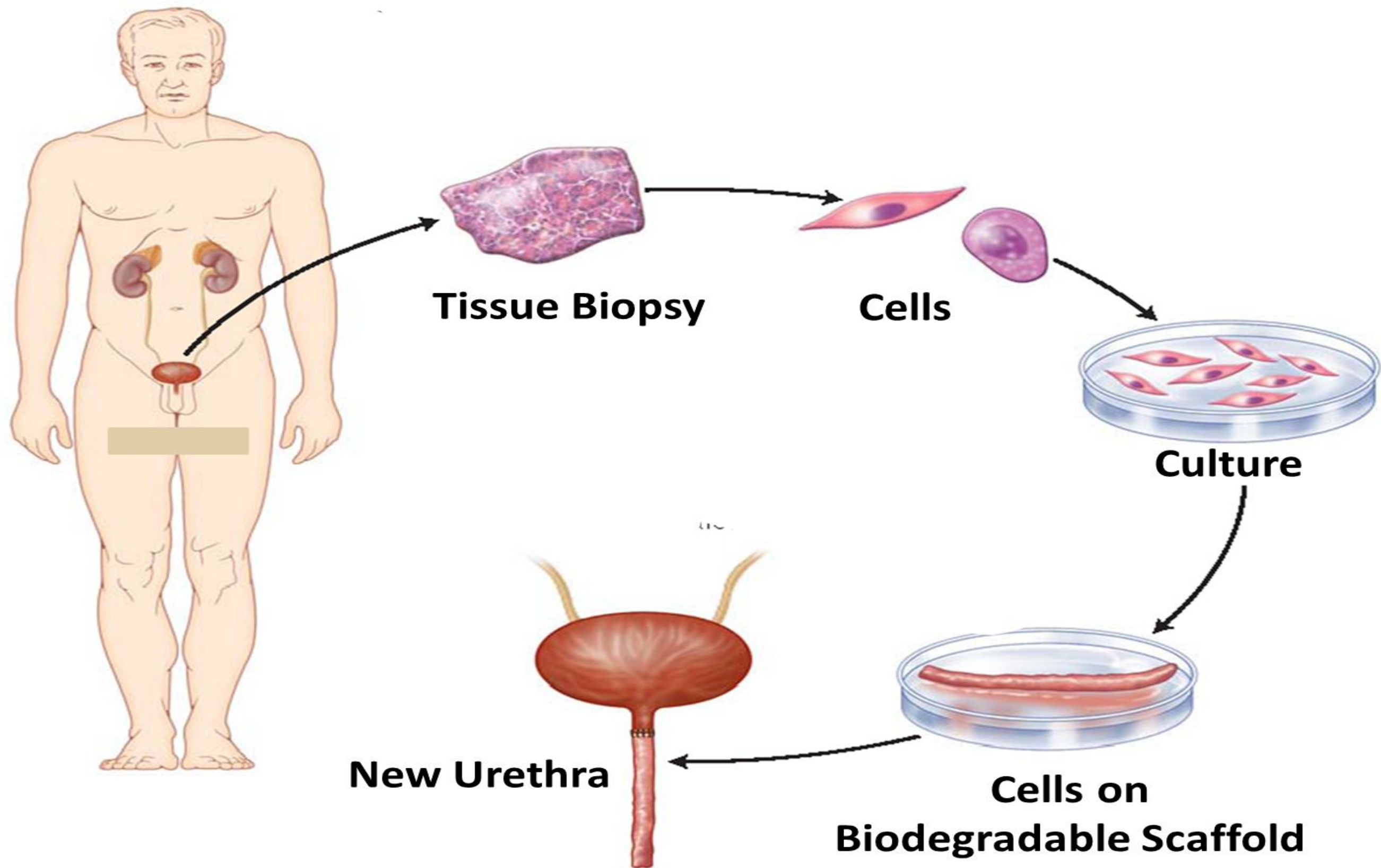


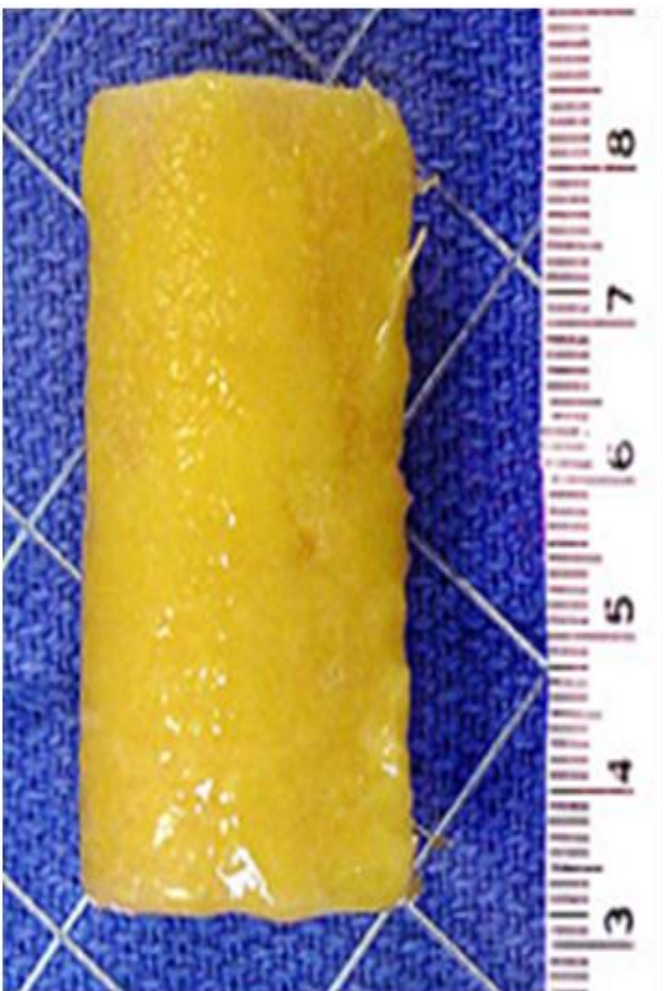
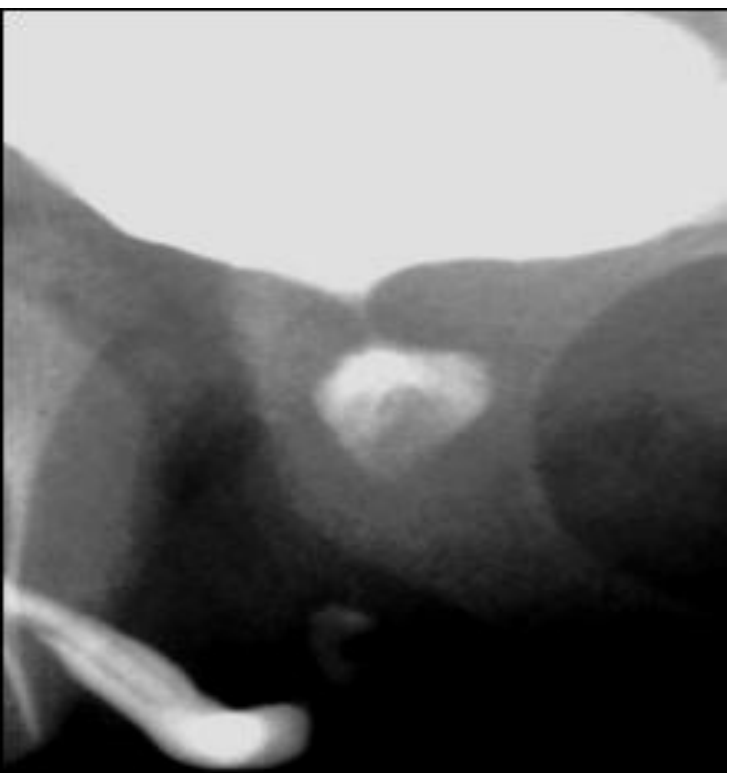
- Skin cells sprayed
- onto burn area

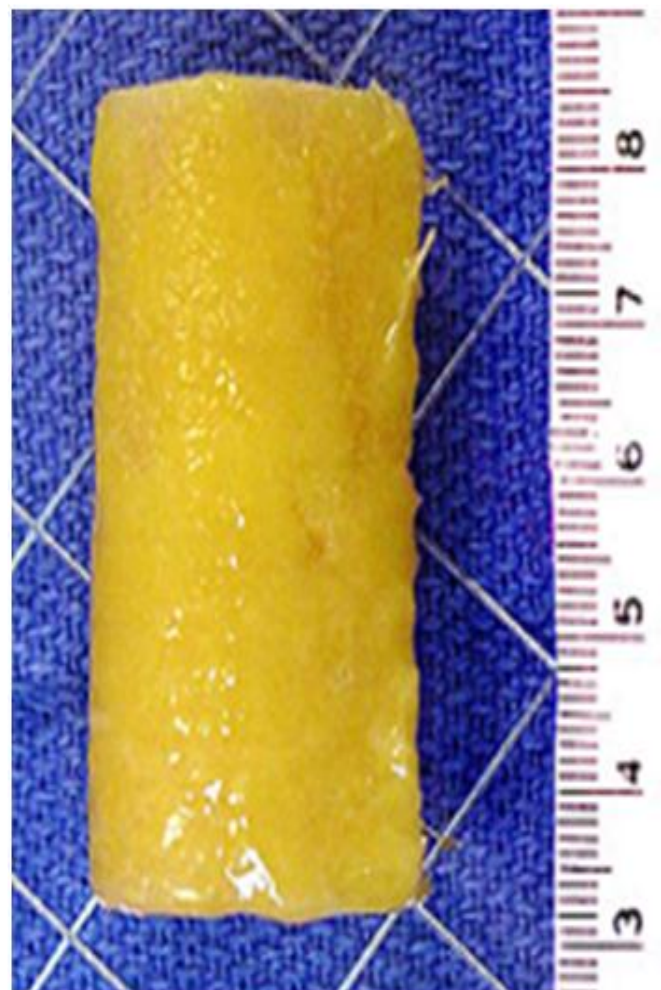
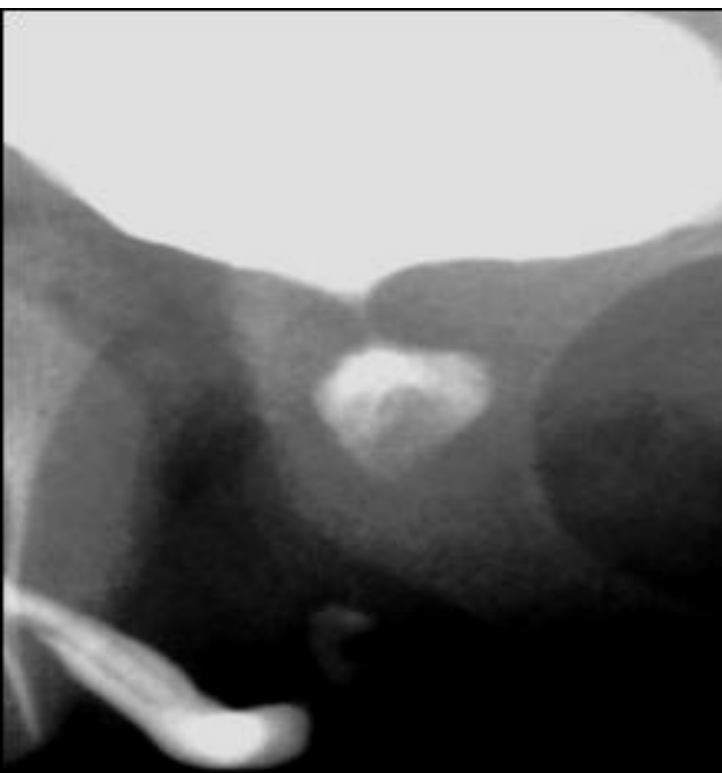












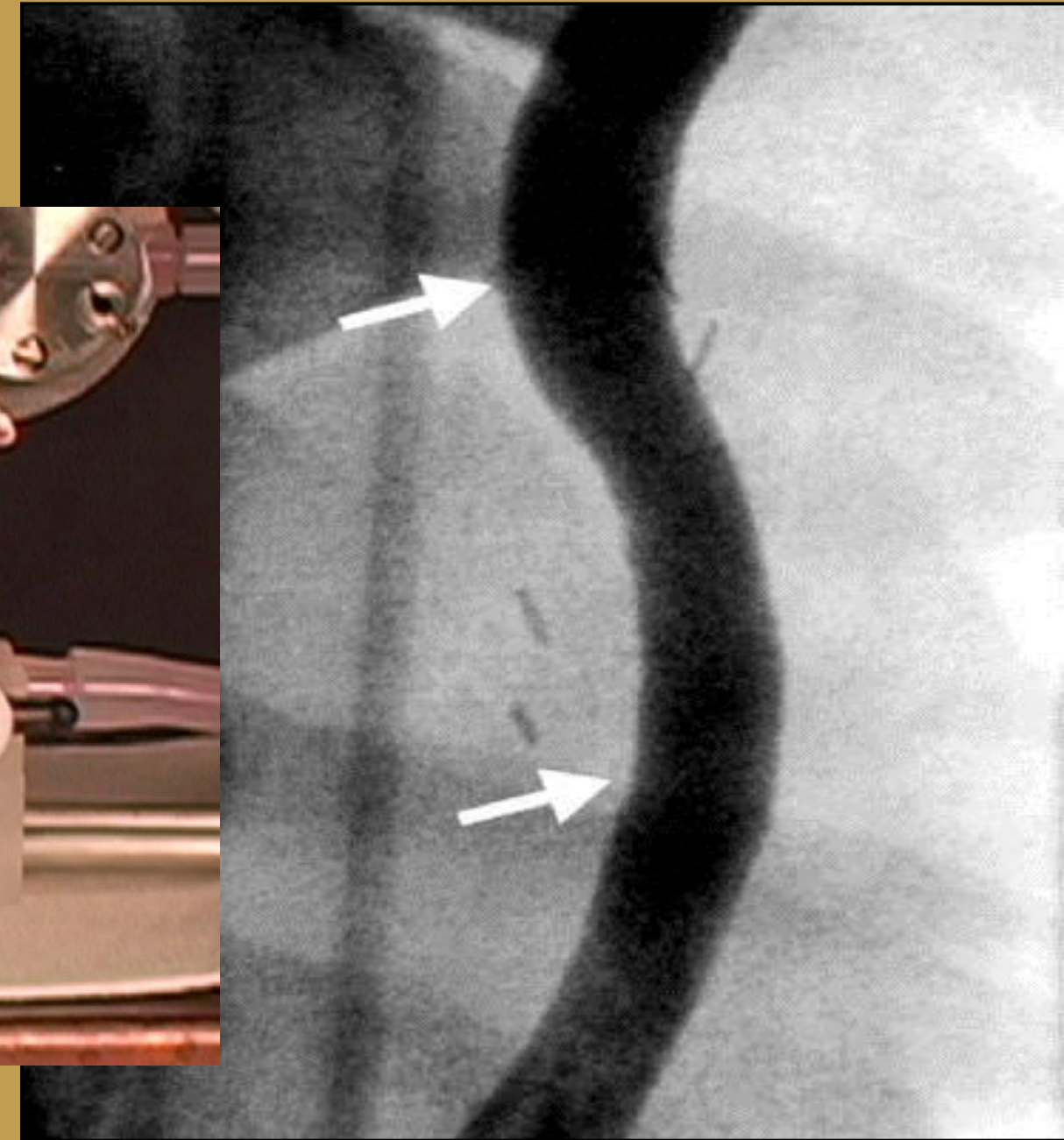
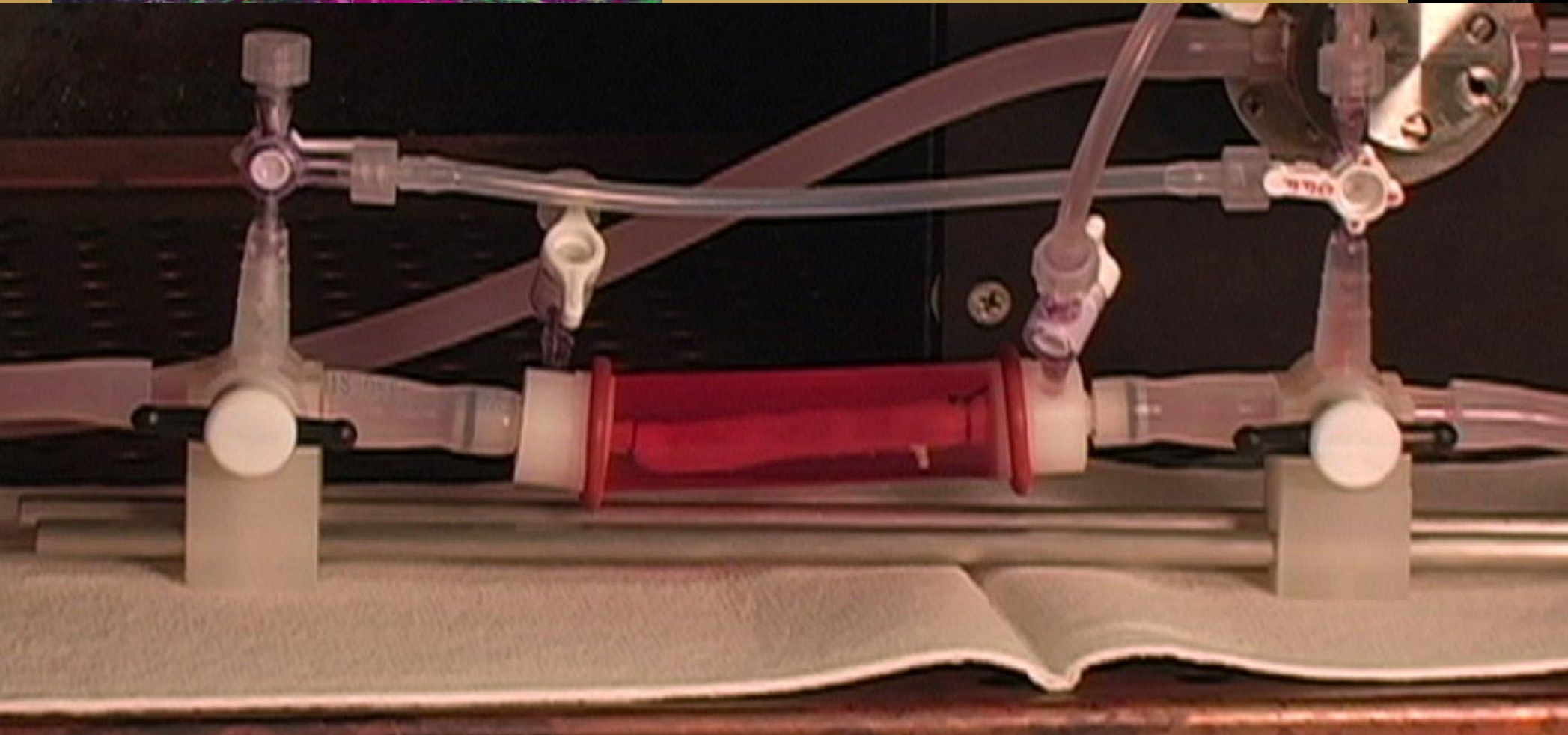
THE LANCET.

**Tissue-engineered
autologous urethras
for patients who
need reconstruction**

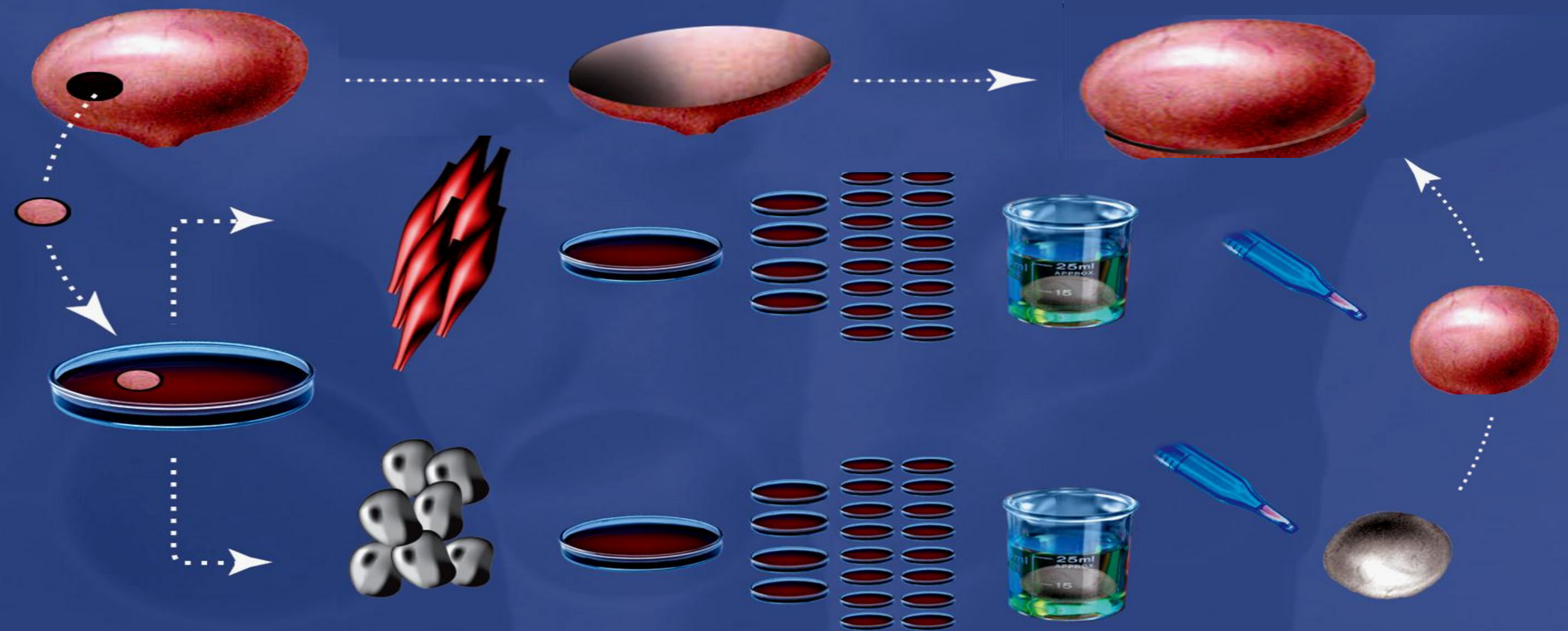
March 2011



Engineered Blood Vessel



Creation of first engineered organ: **BLADDER**



6-8 WEEKS

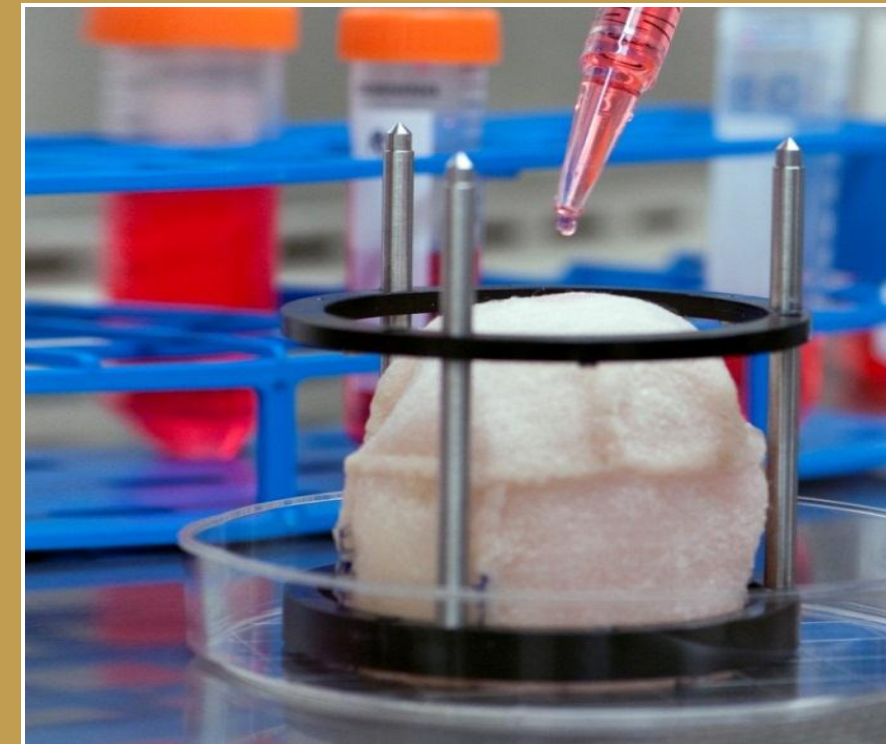
First Engineered Organ in Humans: Bladder



THE LANCET

“Tissue-engineered autologous bladders for patients needing cystoplasty”

April 2006



Engineered Heart Valve

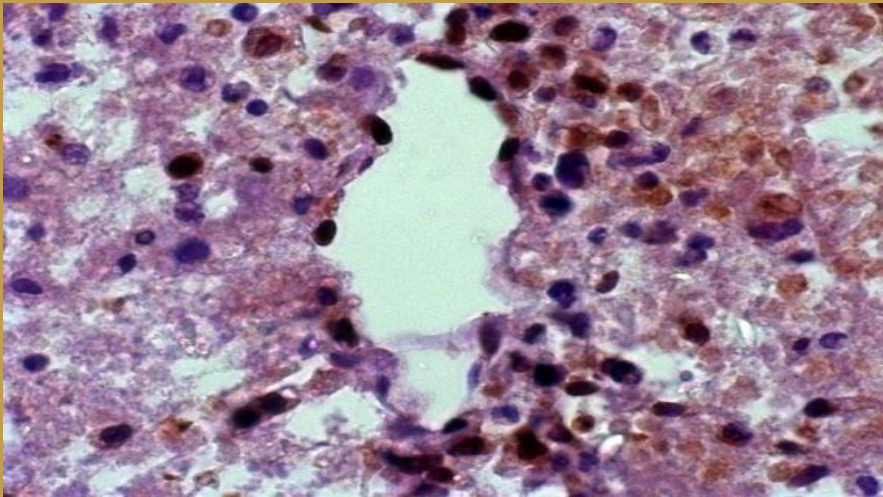
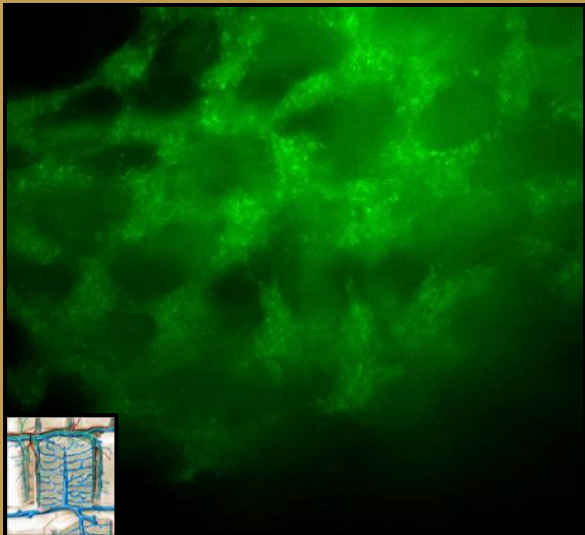
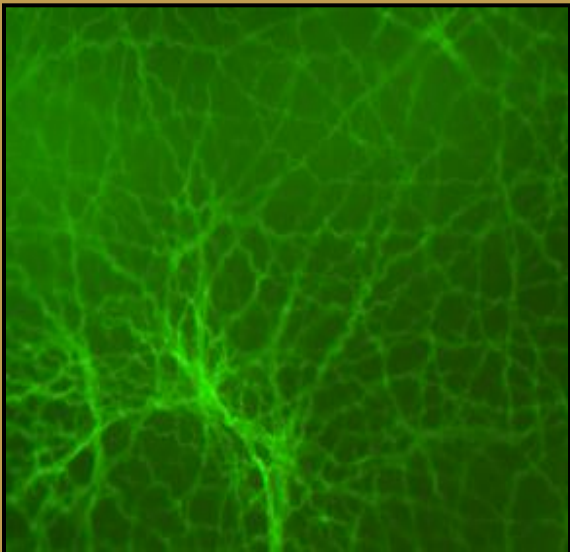
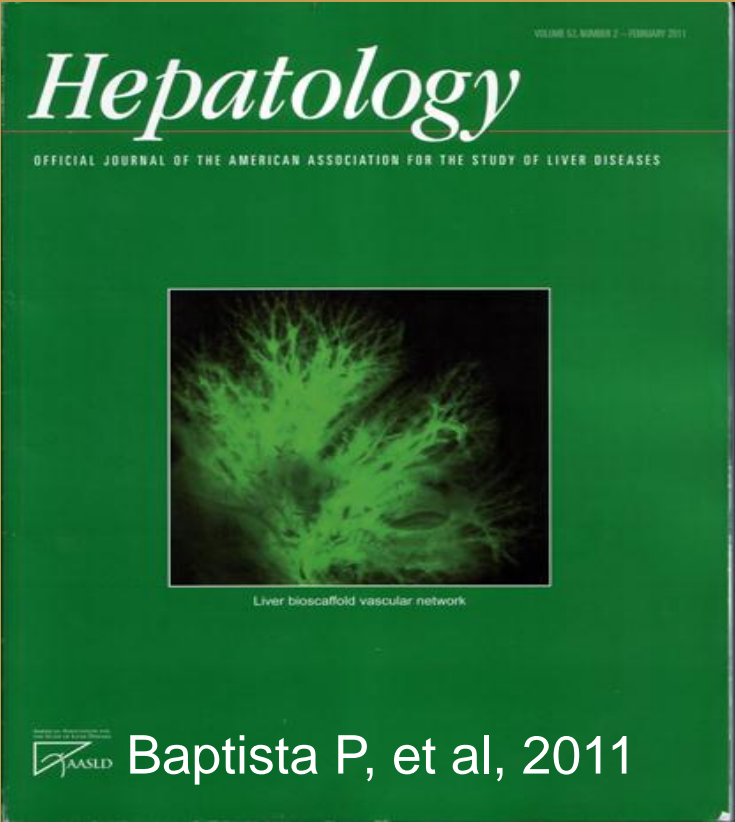


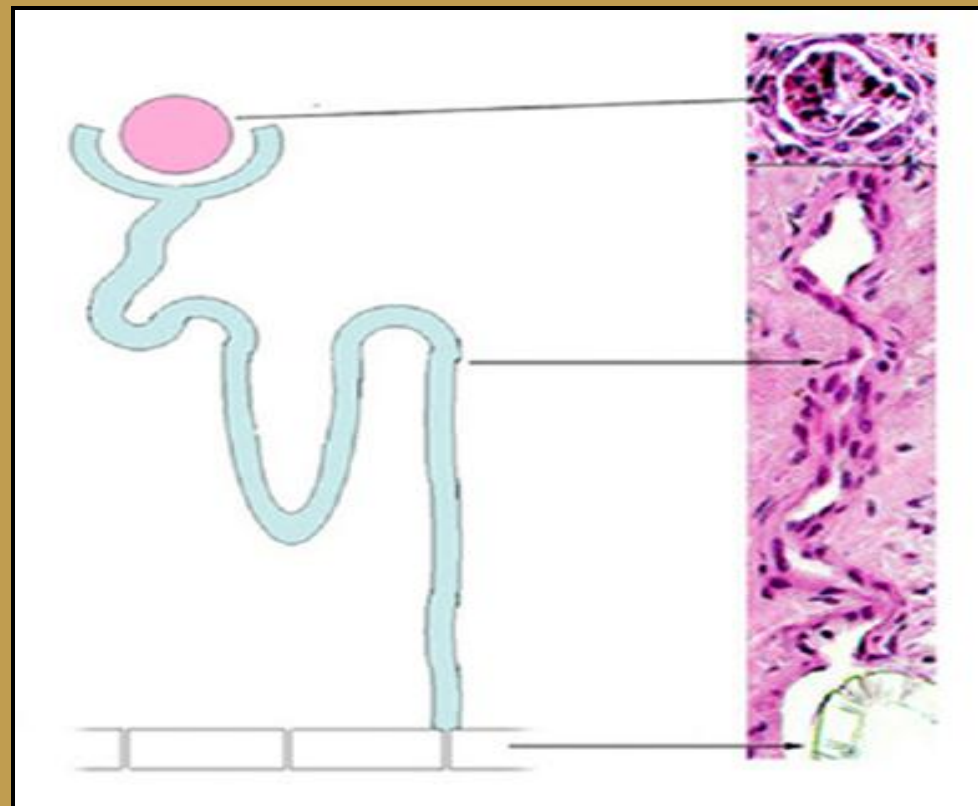
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Liver: First Demonstration of a Functional Engineered Solid Organoid



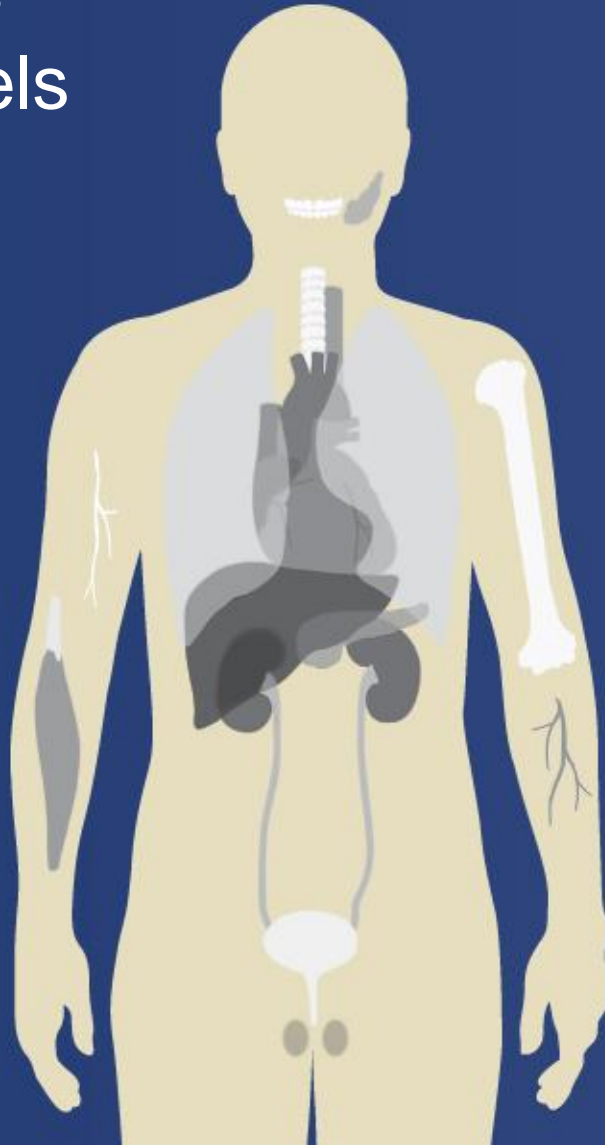


Miniature Engineered Kidneys

Regenerative Medicine

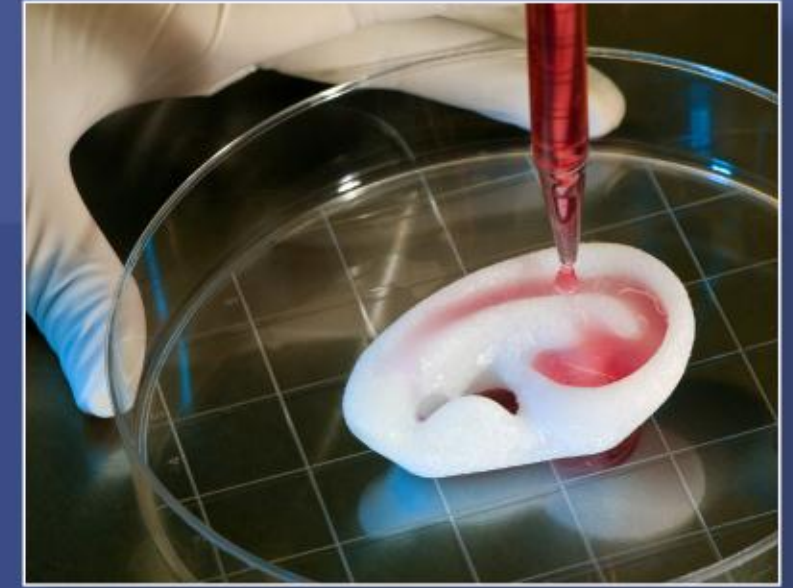
TISSUE ENGINEERING

- Heart valves
- Blood vessels
- Liver
- Muscle
- Skin
- Ears
- Digit



CELL THERAPIES

- Parkinson's Disease
- Diabetes
- Kidney Failure



Over 30 Tissue Types Grown

Approximately 20% now in patients

Another 12 technologies now being translated

Bladder

Blood vessel

Bone

Cartilage

Cornea

Corpora

Diaphragm

Ear

Fascia

Fat

Heart

Heart valve

Intestine

Kidney

Liver

Nasal Turbinate

Nerve

Ovary

Pancreas

Salivary Glands

Skeletal Muscle

Skin

Smooth Muscle

Tendon

Testis

Trachea

Ureter

Urethra

Urinary Sphincter

Uterus

Vagina

Metric	Year Ending 06/30/08	Year Ending 06/30/09	Year Ending 06/30/10	Year Ending 06/30/11	Year Ending 06/30/12
Full time members	127	176	247	260	253
Graduate Students	15	15	25	35	28
Collaborations	104	126	147	194	209
Visitor Groups	86	107	210	351	589
Scientific Publications	111	111	107	146	177
Inventions (cumulative)			85	100	150
Patent Applications (cumulative)			175	200	225
Translational Programs			5	10	12
Extramural Awards			\$22 million	\$30 million	\$32 million

HCEC LLC

Human Corneal Endothelial Cells

- ❖ Piedmont Triad Research Park-based startup
- ❖ Wake Forest, NC Eye Bank, Ocular Systems Inc.
- ❖ Develop bioengineered cornea as substitute for donor corneal tissue
- ❖ Increase quality and availability, decrease cost
- ❖ Preclinical development program conducted at WFIRM

Regenerative Medicine Initiatives

Several State Programs

California

Connecticut

Maryland

Massachusetts

New York

Budgetary Impact

Patient benefits

“...Regenerative medicine will be the standard of care for replacing tissue/organ systems in the human body.”

US Department of Health and Human Services

Health care cost benefits

Because of its potential to cure – rather than merely treat disease – regenerative medicine offers the opportunity to combat rising health care costs. The state of Michigan, similar in size to North Carolina, estimates it could save \$80 million per year if regenerative medicine therapies reduced health care costs and lost productivity by just ONE PERCENT.

Regenerative Medicine Accelerator

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graph TD; A[Regenerative Medicine Accelerator] --> B[Pre-Clinical Facility]; A --> C[Translation]; A --> D[Patients]; B --> E[Regulatory Affairs]; E --> F[GMP FDA Approved Facility]; F --> D;
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The diagram illustrates the workflow of a Regenerative Medicine Accelerator. It begins with a central horizontal bar at the top labeled 'Regenerative Medicine Accelerator'. Three large downward-pointing arrows lead from this bar to three main components: 'Pre-Clinical Facility' (left), 'Translation' (center), and 'Patients' (right). The 'Translation' component is represented by a brown rectangular box, while the others are teal ovals. Below 'Pre-Clinical Facility', an arrow points to 'Regulatory Affairs' (teal oval). An arrow then points from 'Regulatory Affairs' to 'GMP FDA Approved Facility' (teal oval). Finally, an arrow points from 'GMP FDA Approved Facility' up to 'Patients'.

**Pre-Clinical
Facility**

Translation

Patients

**Regulatory
Affairs**

**GMP FDA
Approved
Facility**

Leverage for Federal Funding

Armed Forces Institute for Regenerative Medicine (AFIRM I)

Craniofacial reconstruction

Extremity injury

Scarless wound healing

Burns

Approximately 10 clinical trials currently active in AFIRM I

Navy Research

Other (DARPA, Homeland Security, etc.)

AFIRM II



Mission

*Improve patients lives by developing
regenerative medicine therapies
and support technologies*

Luke M, Years After Receiving his Engineered Organ

